

CLOSURE FOR ROD RECEIVING ORTHOPEDIC IMPLANTHAVING LEFT HANDED THREAD REMOVALCross-Reference to Related Application

This is a continuation-in-part of co-pending U.S. Patent Application, Serial No. 10/236,123 filed September 6, 2002 for HELICAL WOUND MECHANICALLY INTERLOCKING MATING GUIDE AND ADVANCEMENT STRUCTURE, which is now U.S. Patent No. \_\_, \_\_, \_\_.

Background of the Invention

1       The present invention is directed to a closure for  
2       operably securing a rod to an orthopedic implant wherein  
3       said closure includes a break off head, a left hand threaded  
4       axially aligned bore for use in removal of the closure from  
5       the implant and a structure for use in interlocking together  
6       the closure and the implant. The interlocking structure  
7       includes a first interlocking form on the closure and a  
8       mating second interlocking form on the implant. The closure  
9       is operably rotated into the implant and against the rod for  
10      securing the rod in the implant. The first and second  
11      interlocking forms are both helically wound so that the

1 first interlocking form advances relative to the second  
2 interlocking form and toward the rod, when the closure with  
3 the first interlocking form is inserted in the implant and  
4 rotated. At least one of the first or second interlocking  
5 forms includes a projection that overlaps and radially locks  
6 with the other interlocking form, when the two forms are  
7 mated.

8 Medical implants present a number of problems to both  
9 surgeons installing the implants and to engineers designing  
10 them. It is always desirable to have an implant that is  
11 strong and unlikely to fail or break during usage. It is  
12 also desirable for the implant to be as small and  
13 lightweight as possible so that it is less intrusive on the  
14 patient. These are normally conflicting goals and often  
15 difficult to resolve.

16 One particular type of implant presents special  
17 problems. In particular, spinal bone screws, hooks, etc.  
18 are used in many types of back surgery for repair of injury,  
19 disease or congenital defect. For example, spinal bone  
20 screws of this type are designed to have one end that  
21 inserts threadably into a vertebra and a head at an opposite  
22 end thereof. The head is designed to receive a rod or rod-  
23 like member in a channel in the head. The rod is then both

1 captured in the channel and locked in the head to prevent  
2 relative movement between the various elements subsequent to  
3 installation.

4       There are two different major types of bone screws and  
5 similar devices which are classified as closed headed and  
6 open headed. While the closed headed devices are highly  
7 effective at capturing and securing a rod, it is very  
8 difficult during surgery to insert the rod through the  
9 heads, since the rod must be introduced through an opening  
10 in the head. This is because there are many bone screw  
11 heads used and the rod is often curved or the heads do not  
12 align. Consequently, the more screw heads that the rod must  
13 pass through, the more difficult it is to manipulate the rod  
14 into and through them.

15       The second type of head is an open head wherein a  
16 channel is formed in the head and the rod is simply laid in  
17 an open channel. The channel is then closed with a closure  
18 member. The open headed bone screws and related devices are  
19 much easier to use and in some situations must be used  
20 instead of the closed headed devices.

21       While the open headed devices are often necessary and  
22 often preferred for usage, there is a significant problem  
23 associated with them. In particular, the open headed

1 devices conventionally have two upstanding arms that are on  
2 opposite sides of a channel that receives the rod member.  
3 The top of the channel is closed by a closure member after  
4 the rod member is placed in the channel. Forces applied  
5 during installation or during accidents can cause the arms  
6 to splay or spread at the top which may result in failure of  
7 the implant if the arms splay sufficiently to loosen or  
8 release the closure. The closure can be of a slide in type,  
9 but such are not easy to use. Threaded nuts are sometimes  
10 used that go around the outside of the arms. Such nuts  
11 prevent splaying of the arms, but nuts substantially  
12 increase the size and profile of the implant which is not  
13 desirable. Many open headed implants are closed by plugs  
14 that screw into threads between the arms, because such have  
15 a low profile. However, threaded plugs have encountered  
16 problems also in that they especially produce forces that  
17 are radially outward directed and that lead to splaying or  
18 spreading of the arms or at least do not prevent splaying  
19 due to other causes that in turn loosens or completely  
20 releases the rod relative to the implant. In particular, in  
21 order to lock the rod member in place, a significant force  
22 must be exerted on the relatively small plug or screw. The  
23 forces are required to provide enough torque to insure that

1 the rod member is clamped or locked in place relative to the  
2 bone screw, so that the rod does not move axially or  
3 rotationally therein. This typically requires torques on  
4 the order of 100 inch-pounds.

5 Because open headed implants such as bone screws, hooks  
6 and the like are relatively small, the arms that extend  
7 upwardly at the head can be easily bent by radially outward  
8 directed forces due to the application of substantial forces  
9 required to lock the rod member. Historically, early  
10 closures were simple plugs that were threaded with V-shaped  
11 threads and which screwed into mating threads on the inside  
12 of each of the arms. But, as noted above, conventional V-  
13 shaped threaded plugs exert radially outward forces and tend  
14 to splay or push the upper ends of the arms radially outward  
15 upon the application of a significant amount of torque,  
16 which ends up bending the arms relative to a body  
17 sufficiently to allow the threads to loosen or disengage  
18 from each other and the closure to loosen and/or disengage  
19 from the implant and thereby fail. To counter splaying,  
20 various engineering techniques were applied to allow the  
21 head to resist the spreading force. For example, in one  
22 attempt, the arms were significantly strengthened by  
23 increasing the width of the arms a significant amount. This

1 had the unfortunate effect of substantially increasing the  
2 weight and the profile of the implant, which was  
3 undesirable.

4 Many prior art devices have also attempted to provide  
5 outside rings or some other type of structure that goes  
6 about the outside of the arms to better hold the arms in  
7 place either independently or while a center plug was  
8 installed and thereafter. This additional structure may  
9 cause the locking strength of the plug against the rod to be  
10 reduced which is undesirable, especially when additional  
11 structure is partly located between the plug and the rod, as  
12 is the case in some devices. Also, the additional elements  
13 are unfavorable from a point of view of implants, since it  
14 is typically desirable to maintain the number of parts  
15 associated with the implants at a minimum and, as noted  
16 above, to keep the profile, bulk and weight as minimal as  
17 possible.

18 Prior designers have also attempted to resolve the  
19 splaying problem by providing a closure with a pair of  
20 opposed radially extending wedges or flanges that are  
21 designed to twist ninety degrees and that have mating  
22 structure in the arms of the implant. Such devices serve as  
23 a closure and do somewhat resist splaying of the arms, but

1 are often very difficult to use. In particular, the rods  
2 normally have some curvature as the rods are bent to follow  
3 the curvature of the spine and normally bow relative to the  
4 bottom of the bone screw channel that receives such a rod.  
5 The rod thus fills much of the channel and must be "unbent"  
6 to rest on the bottom of the channel or pushed toward the  
7 bottom of the channel and held securely in place.  
8 Therefore, the rod is preferably compressed and set by the  
9 plug by advancement of the plug into the channel in order to  
10 assure that the plug will securely hold the rod and that the  
11 rod and plug will not loosen when post assembly forces are  
12 placed on the rod. Because it takes substantial force to  
13 seat the rod, it is difficult to both place the plug fully  
14 in the channel and rotate the plug for locking while also  
15 trying to line up wedges on the plug with the mating  
16 structure. It is much easier to align the closure plug or  
17 mating structure with the mating structure of the arms at  
18 the top of the arms and then rotate the plug so as to  
19 advance the plug in a plug receiver toward the rod. In this  
20 way, the plug starts applying significant force against the  
21 rod only after parts of the mating structure have at least  
22 partly joined at which time torque can be applied without  
23 having to worry about alignment. It is also noted that in

1 prior art plugs where wedges are used, the cross section of  
2 the structure changes therealong so that the device "locks  
3 up" and cannot turn further after only a small amount of  
4 turning, normally ninety degrees.

5 Consequently, a lightweight and low profile closure  
6 plug is desired that resists splaying or spreading of the  
7 arms while not requiring significant increases in the size  
8 of the screw or plug heads and not requiring additional  
9 elements that encircle the arms to hold the arms in place.

10 It is noted that the tendency of the open headed bone  
11 screw to splay is a result of the geometry or contour of the  
12 threads typically employed in such devices and the inability  
13 of threads to timely interlock with each other or a mating  
14 structure. In the past, most bone screw head receptacles  
15 and screw plugs have employed V-shaped threads. V-threads  
16 have leading and trailing sides oriented at angles to the  
17 screw axis. Thus, torque on the plug is translated to the  
18 bone screw head at least partially in an axial direction,  
19 tending to push or splay the arms of the bone screw head  
20 outward in a radial direction. This in turn spreads the  
21 arms of an internally threaded receptacle away from the  
22 thread axis so as to loosen the plug in the receptacle.



1       The radial expansion problem of V-threads has been  
2 recognized in various types of threaded joints. To overcome  
3 this problem, so-called "butfress" threadforms were  
4 developed. In a buttfress thread, the trailing or thrust  
5 surface is oriented perpendicular to the thread axis, while  
6 the leading or clearance surface remains angled. This  
7 theoretically results in a neutral radial reaction of a  
8 threaded receptacle to torque on the threaded member  
9 received.

10       Development of threadforms proceeded from buttfress  
11 threadforms which in theory have a neutral radial effect on  
12 the screw receptacle to reverse angled threadforms which  
13 theoretically positively draw the threads of the receptacle  
14 radially inward toward the thread axis when the plug is  
15 torqued. In a reverse angle threadform, the trailing side  
16 of the external thread is angled toward the thread axis  
17 instead of away from the thread axis, as in conventional V-  
18 threads. While buttfress and reverse threadforms reduce the  
19 tendency to splay, the trailing and leading surfaces of such  
20 a threadform are linear allowing opposing sides to slide  
21 relative to the surfaces so that the arms can still be bent  
22 outward by forces acting on the implant and the threads can  
23 be bent by forces exerted during installation. Therefore,

1 while certain threadforms may not exert substantial radial  
2 forces during installation, at most such threadforms provide  
3 an interference or frictional fit and do not positively lock  
4 the arms in place relative to the closure plug.

5 It is also noted that plugs of this type that use  
6 threadforms are often cross threaded. That is, as the  
7 surgeon tries to start the threaded plug into the threaded  
8 receiver, the thread on the plug is inadvertently started in  
9 the wrong turn or pass of the thread on the receiver. This  
10 problem especially occurs because the parts are very small  
11 and hard to handle. When cross threading occurs, the plug  
12 will often screw partially into the receiver and then "lock  
13 up" so that the surgeon is led to believe that the plug is  
14 properly set. However, the rod is not tight and the implant  
15 fails to function properly. Therefore, it is also desirable  
16 to have a closure that resists crossthreading in the  
17 receiver.

18 For closures of the type described herein to function  
19 properly, such closures are "set" or torqued to a preferred  
20 torque, often 95 to 100 inch pounds. The operating region  
21 where the implants are installed is within the body and the  
22 parts are relatively very small. Consequently, the closures  
23 of the present invention preferably can be readily gripped

1 and torqued. In order to reduce profile, a driving or  
2 installation head is designed to break away at a preselected  
3 torque.

4 After the closure is installed, it is sometimes  
5 necessary to remove the closure. For purposes of removal,  
6 the driving head is no longer available, so structure is  
7 required to allow quick easy removal and which cooperates  
8 effectively with the guide and advancement structure  
9 utilized with the closure.

10

#### 11 Summary of the Invention

12

13 A non threaded guide and advancement structure is  
14 provided for securing a plug or closure in a receiver in an  
15 orthopedic implant. The receiver is a rod receiving channel  
16 in an open headed bone screw, hook or other medical implant  
17 wherein the channel has an open top and is located between  
18 two spaced arms of the implant.

19 The guide and advancement structure has a first part or  
20 interlocking form located on the closure and a second part  
21 or interlocking form that is located on the interior of the  
22 receiving channel. The interlocking forms lock and resist  
23 sidewise or radial movement of load bearing leading or

1 trailing surfaces rather than simply interfere with movement  
2 due to placement.

3 Both parts of the guide and advancement structure are  
4 spirally or more preferably helically wound and extend about  
5 the closure and receiving channel for at least one complete  
6 360° pass or turn. Preferably, both parts include multiple  
7 turns such as 2 to 4 complete 360° rotations about the  
8 helixes formed by the parts. The helixes formed by the  
9 parts are coaxial with the closure when the closure is fully  
10 received in or being rotated into the receiving channel  
11 between the arms.

12 One major distinguishing feature of the guide and  
13 advancement structure is that each of the parts include  
14 elements that mechanically interlock with the opposite part  
15 or mating piece as the closure is rotated and thereby  
16 advanced into the receiving channel toward the bottom of the  
17 channel and into engagement with a rod received in the  
18 channel.

19 Each part of the guide and advancement structure  
20 preferably has a generally constant and uniform cross  
21 section, when viewed in any cross sectional plane fully  
22 passing through the axis of rotation of the closure during  
23 insertion, with such uniform cross section preferably

1 extending along substantially the entire length of the  
2 interlocking form. Opposite ends of each interlocking form  
3 are feathered or the like so the cross section does change  
4 some at such locations, while retaining part of the overall  
5 shape. In particular, the outer surfaces of each  
6 interlocking form remain sufficiently uniform to allow  
7 interlocking forms to be rotated together and slide  
8 tangentially with respect to each other through one or more  
9 complete turns of the closure relative to the receiving  
10 channel. Each part may be continuous from near a bottom of  
11 the closure or receiving channel to the top thereof  
12 respectively. In certain circumstances one or both parts  
13 may be partly discontinuous, while retaining an overall  
14 helical configuration with a generally uniform cross  
15 sectional shape. When the interlocking form has multiple  
16 sections due to being discontinuous, each of the sections  
17 has a substantially uniform cross section along  
18 substantially the entire length thereof.

19 In order to provide an interlocking structure, the  
20 parts of the structure include helical wound projections or  
21 interlocking forms that extend radially outward from the  
22 closure and radially inward from the receiving channel. The  
23 interlocking forms may be of many different shapes when

1 viewed in crossection with respect to a plane passing  
2 through the axis of rotation of the plug during insertion.  
3 In general, the interlocking forms increase in axial aligned  
4 width or have a depression at a location spaced radially  
5 outward from where the interlocking form attaches to a  
6 respective closure or receiving channel, either upward (that  
7 is, parallel to the axis of rotation of the closure in the  
8 direction from which the closure comes or initially starts)  
9 or downward or in both directions. This produces a first  
10 mating element that is in the form of a protrusion, bump,  
11 ridge, elevation or depression on the interlocking form that  
12 has a gripping or overlapping portion. The opposite  
13 interlocking form has a second mating element with a  
14 gripping or overlapping portion that generally surrounds or  
15 passes around at least part of the first mating element in  
16 such a way that the two are radially or sideways  
17 mechanically locked together when the closure is advanced  
18 into the receiving channel.

19 Therefore, in accordance with the invention a mating  
20 and advancement structure is provided for joining two  
21 devices, that are preferably medical implants and especially  
22 are an open headed implant that includes a rod receiving  
23 channel and a closure for closing the receiving channel

1 after the rod is received therein. The mating and  
2 advancement structure includes a pair of mateable and  
3 helical wound interlocking forms with a first interlocking  
4 form located on an outer surface of the closure and a second  
5 interlocking form located on an inner surface of the  
6 receiving channel or receiver. The first and second  
7 interlocking forms are startable so as to mate and  
8 thereafter rotatable relative to each other about a common  
9 axis so as to provide for advancement of the closure into  
10 the receiver during assembly when the closure interlocking  
11 form is rotated into the receiver interlocking form. The  
12 first and second interlocking forms have a helical wound  
13 projection that extends radially from the closure and the  
14 receiver respectively. Each interlocking form projection  
15 has a base that is attached to the closure or receiver  
16 respectively and preferably includes multiple turns that may  
17 each be continuous or partially discontinuous with constant  
18 or uniform cross-sectional shape. The interlocking forms  
19 have substantial axial width near an outer end thereof that  
20 prevents or resists misalignment of the interlocking form  
21 during initial engagement and rotation thereof.

22 After assembly, in some embodiments each turn of each  
23 projection generally snugly engages turns of the other

1 projection on either side thereof. In other embodiments  
2 there must be sufficient tolerances for the parts to slide  
3 tangentially, so that when thrust surfaces of the  
4 interlocking forms are very close during tightening, some  
5 gap occurs on the leading side of the closure interlocking  
6 form. In such a case the portions of the interlocking forms  
7 on the thrust side thereof lock together and prevent radial  
8 splaying.

9        Located radially spaced from where the base of each  
10 projection is attached to either the closure or receiver  
11 respectively, is an axially extending (that is extending in  
12 the direction of the axis of rotation of the plug or  
13 vertically) extension or depression. The opposite or mating  
14 interlocking form has elements that wrap around or into such  
15 extensions or depressions of the other interlocking form.  
16 That is, the forms axially interdigitate with each other and  
17 block radial outward movement or expansion. In this way and  
18 in combination with the interlocking forms preferably being  
19 snug or close relative to each other with sufficient  
20 clearance to allow rotation, the interlocking forms, once  
21 assembled or mated lock to prevent radial or sideways  
22 slipping or sliding relative to each other, even if forces  
23 are applied that would otherwise bend the base of one or



1 both relative to the device upon which it is mounted. It is  
2 possible that the cross section of the projection (in a  
3 plane that passes through the plug axis of rotation of the  
4 closure) of each section of each turn or pass of the  
5 interlocking form be the same, although this is not required  
6 in all embodiments. For example, part of the interlocking  
7 form may be missing in the region between opposed arms when  
8 assembly is complete as this area is not required to hold  
9 the arms together.

10 Preferably, the present invention provides such an  
11 interlocking form for use in a medical implant closure which  
12 resists splaying tendencies of arms of a receiver. The  
13 interlocking form of the present invention preferably  
14 provides a compound or "non-linear" surface on a trailing  
15 face, thrust face or flank of the interlocking form,  
16 although the "non-linear" surface may also be placed on the  
17 leading face.

18 Preferably, the interlocking form located on the  
19 closure is helically wound about a cylindrical outer surface  
20 of the closure and has an inner root, and an outer crest  
21 that remain constant over substantially the entire length of  
22 the interlocking form. The receiver has a mating or similar  
23 shaped interlocking form wound about the interior thereof.

1 In this embodiment the interlocking form has leading or  
2 clearance surfaces and trailing or thrust surfaces,  
3 referenced to the direction of axial movement of the form  
4 when rotated into one another. The structure also includes  
5 an internal helical wound interlocking form located on an  
6 internal surface of a receiver member and has an outer root  
7 and an inner crest. The internal interlocking form has  
8 thrust surfaces which are oriented in such a direction so as  
9 to be engaged by the thrust surfaces of the external  
10 interlocking form of a member engaged therewith.

11 In certain embodiments, the thrust surfaces are "non-  
12 linear" or compound. That is, the thrust surfaces have a  
13 non-linear appearance when represented in cross section.  
14 The purpose for the non-linear or compound surface is to  
15 provide a portion of the thrust surface which is oriented in  
16 such a direction so as to resist a tendency of the receiver  
17 to expand or splay when tightening torque is applied to  
18 rotate the interlocking forms into a mating relationship or  
19 when other forces are encountered. As applied to a closure  
20 for an open headed bone implant screw, the non-linear or  
21 compound surfaces of the interlocking forms whether on  
22 tracking surfaces, leading surfaces or both interlock and  
23 resist splaying tendencies of the arms of the head. The

1 objective of the interlocking form is not necessarily to  
2 generate a radially inwardly directed force on the  
3 receptacle in tightening the fastener (although this may  
4 occur in some embodiments), but importantly to resist  
5 outward forces generated by engagement of the closure with  
6 the closure receptacle or by other forces applied to the  
7 components joined by the closure and closure receptacle and  
8 prevent splaying. It is noted that the present invention  
9 requires that only a portion of the thrust surfaces of a  
10 closure be so configured as to face toward the closure axis  
11 and only a portion of thrust surfaces of a closure  
12 receptacle face away from the axis.

13 In certain embodiments, an axial extension or  
14 depression is located on the thrust or trailing surface, or  
15 alternatively for such to be located on the opposite or  
16 leading surface or both.

17 Further, in some embodiments a section of the  
18 interlocking form at the crest, that is located radially  
19 outward of the root, is enlarged in cross sectional area to  
20 create a gripping, locking or stopping surface that resists  
21 slippage or sliding in a radial direction relative to an  
22 opposed interlocking form. In a complementary manner, a  
23 section of the interlocking form between the root and the

1 crest which is radially spaced from the root is enlarged in  
2 cross sectional area to create a gripping, locking or  
3 stopping surface that engages a like surface of the opposite  
4 interlocking form. The enlarged sections of the inner and  
5 outer interlocking forms are created by cutting, molding,  
6 machining or the like grooves or channels or the like into a  
7 radially inward portion of the thrust surface of the  
8 external interlocking form and mating grooves or channels  
9 into a radially outward portion of the thrust surface of the  
10 internal interlocking form. Such grooves or channels may be  
11 formed by specially shaped taps and dies, cutting elements  
12 or by other suitable manufacturing processes and  
13 technologies, including molding.

14 The interlocking forms of the present invention may be  
15 implemented in a variety of configurations of non-linear,  
16 compound, or complex trailing and/or leading surfaces. The  
17 nomenclature used to describe variations in the interlocking  
18 forms of the present invention is especially referenced to  
19 the external interlocking forms located on a closure, with  
20 complementary, mating or similar shapes applied to the  
21 internal interlocking forms on a receiver. In an axial  
22 shoulder interlocking form of the present invention, a  
23 somewhat squared gripping shoulder is formed near an outer

1 periphery of the external interlocking forms and an inner  
2 gripping surface on the internal interlocking forms. The  
3 axial shoulder interlocking form results in complementary  
4 cylindrical surfaces on the external and internal  
5 interlocking forms which mutually engage when the fastener  
6 or closure is rotated into a closure receptacle.

7       In an axial extending bead interlocking form, the  
8 external interlocking form is provided with a rounded  
9 peripheral bead or lateral lip which projects in an axial  
10 direction along the interlocking form crest and a  
11 complementary rounded concave channel in the internal  
12 interlocking form. The reverse occurs with the internal  
13 interlocking form.

14       Other alternative forms include a radial bead  
15 interlocking form wherein a rounded bead enlargement is  
16 formed on the radially outward periphery at the crest of the  
17 external interlocking form, while the internal interlocking  
18 form is formed in a complementary manner to receive the  
19 radial bead interlocking form. A scalloped or scooped  
20 interlocking form which is, in effect, a reciprocal of the  
21 axial bead interlocking form and has a rounded channel or  
22 groove located along the thrust surface of the external  
23 interlocking form with a complementary rounded convex bead

1 shape associated with the internal interlocking form. A  
2 variation of the axial bead interlocking form is a medial  
3 bead embodiment. In the medial bead interlocking form, a  
4 bead projects from a base thrust surface of an external  
5 interlocking form in an axial direction at a location  
6 medially between the root and crest of the interlocking  
7 form. In a complementary medial bead internal interlocking  
8 form, an axial groove is formed in a base thrust surface  
9 between the root and crest. In a medial groove interlocking  
10 form, an axial groove is formed in a base thrust surface of  
11 the external interlocking form medially between the root and  
12 crest, while the internal interlocking form has an axial  
13 bead located medially between the root and crest.

14 Variations in the above described interlocking forms  
15 are envisioned with respect to relative extensions or  
16 enlargements and depressions or depth of grooves of the  
17 various interlocking forms. In some variations, the  
18 opposite interlocking forms have the same but reversed and  
19 inverted cross section, whereas in others the cross section  
20 of the paired interlocking forms mates but is different. It  
21 is noted that many other configurations of interlocking  
22 forms with non-linear, compound or complex thrust surfaces

1 are envisioned, which would be encompassed by the present  
2 invention.

3       The interlocking forms of the present invention find  
4 particularly advantageous application in various types of  
5 bone implant devices. The interlocking forms also have  
6 advantages in reducing misalignment problems of cross-  
7 interlocking and misinterlocking of interlocking forms when  
8 the opposed interlocking forms are joined and rotated which  
9 is commonly encountered in such devices when threads of  
10 various types are used.

11       A breakoff head is provided for rotating and driving  
12 the closure along the axis of the receiver. The breakoff  
13 head is axially secured to the closure and breaks from the  
14 remainder of the closure after the closure is set against a  
15 rod and a predetermined torque is obtained, for example 100  
16 inch pounds.

17       Axially penetrating the closure from the top thereof  
18 and being fully exposed by the breakoff head being broken  
19 therefrom is a bore. The bore may be fully penetrating or  
20 partially penetrating from top to bottom of the closure.  
21 The bore has an interior left handed thread that is sized  
22 and shaped to receive a like threaded tool that can be  
23 rotated counterclockwise after insertion to also rotate the

1 closure body counterclockwise to remove the body should  
2 removal be required after installation.

### 3 4 Objects and Advantages of the Invention

5  
6 Therefore, objects of the present invention include  
7 providing an improved closure plug or closure top for use  
8 with an open headed bone screw; providing such a closure  
9 having a cylindrical base and a driving or installation head  
10 that breaks away from the base at a breakaway region to  
11 provide a low or minimized profile subsequent to  
12 installation of the closure; providing such a closure having  
13 removal structure enabling positive, non-slip engagement of  
14 the closure by a removal tool which securely grips and holds  
15 the closure; providing such a closure having an axially  
16 extending bore that passes through the installation head and  
17 at least into the closure; providing such a closure in which  
18 the bore has an internal left handed thread that is sized  
19 and shaped to receive a removal tool with a matingly  
20 threaded projection; providing such a closure in combination  
21 with an open headed bone implant screw for use in anchoring  
22 a bone fixation structural member, such as a rod; providing  
23 such a closure combination in which the open headed bone



1 screw includes a pair of spaced apart arms forming a rod  
2 receiving channel; providing such a closure combination  
3 including an external guide and advancement flange on the  
4 closure and mating internal guide and mating structure on  
5 inner surfaces of the bone screw head which interlock and  
6 cooperate to resist tendencies of the arms to splay or  
7 diverge when the closure is torqued tightly into clamping  
8 engagement with a rod positioned in the channel or when  
9 outside forces are applied to the structure; providing such  
10 a combination including features to enhance setting  
11 engagement of the closure with a rod in the bone screw  
12 channel; providing such a combination in which a forward end  
13 of the closure is provided with a peripheral cutting cup or  
14 V-ring and point to cut into the surface of the rod when the  
15 closure is securely torqued, to resist translational and  
16 rotational movement of the rod relative to the bone screw;  
17 and providing such an anti-splay closure plug or fastener  
18 which is economical to manufacture, which is secure and  
19 efficient in use, and which is particularly well adapted for  
20 its intended purpose.

21 Other objects and advantages of this invention will  
22 become apparent from the following description taken in  
23 conjunction with the accompanying drawings wherein are set

1    forth, by way of illustration and example, certain  
2    embodiments of this invention.

3            The drawings constitute a part of this specification,  
4    include exemplary embodiments of the present invention, and  
5    illustrate various objects and features thereof.

6

7                    Brief Description of the Drawings

8

9            Fig. 1 is an enlarged perspective view of an anti-splay  
10    closure with a break off driving head in accordance with the  
11    present invention.

12           Fig. 2 is a side elevational view of the closure at a  
13    further enlarged scale.

14           Fig. 3 is a top plan view of the closure.

15           Fig. 4 is a bottom plan view of the closure that  
16    illustrates a V-ring and point on the bottom of the closure.

17           Fig. 5 is a cross sectional view of the closure, taken  
18    on line 5-5 of Fig. 3 and illustrates internal details of  
19    the break off head and an internal threaded bore.

20           Fig. 6 is a fragmentary side elevational view at a  
21    reduced scale of the closure in combination with an open  
22    headed bone screw implant, prior to separation of the break  
23    off head.

1           Fig. 7 is a view similar to Fig. 6 and illustrates  
2       separation of the break off head of the closure due to  
3       exceeding a preselected torque thereon.

4           Fig. 8 is an enlarged top plan view of the closure  
5       within the open headed bone screw subsequent to breaking  
6       away of the break off head.

7           Fig. 9 is an enlarged cross sectional view of the  
8       closure of the present invention, taken along the line 5-5  
9       of Fig. 3 but subsequent to installation in the bone screw  
10      and illustrates details of anti-splay structure of the  
11      closure and bone screw head, further illustrating a removal  
12      tool inserted in the bore for effecting removal of the  
13      closure from the bone screw.

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#### 15                   Detailed Description of the Invention

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17           As required, detailed embodiments of the present  
18      invention are disclosed herein; however, it is to be  
19      understood that the disclosed embodiments are merely  
20      exemplary of the invention, which may be embodied in various  
21      forms. Therefore, specific structural and functional  
22      details disclosed herein are not to be interpreted as  
23      limiting, but merely as a basis for the claims and as a

1 representative basis for teaching one skilled in the art to  
2 variously employ the present invention in virtually any  
3 appropriately detailed structure.

4 Referring to the drawings in more detail, the reference  
5 numeral 1 generally designates an anti-splay closure with a  
6 partial axial bore 2. The closure 1 generally includes a  
7 closure plug or body 4 and a breakaway head 6 for  
8 installation. The closure 4 is used in cooperation with an  
9 open headed bone implant screw 8 (Figs. 6 and 7) to form an  
10 implant anchor assembly 9 to secure or anchor a spinal  
11 fixation member or rod 10 with respect to a bone 12, such as  
12 a vertebra.

13 The bone screw 8 includes a threaded shank 14 for  
14 threadably implanting the screw 8 into the bone 12 and an  
15 open head 16 having a pair of upwardly extending and spaced  
16 apart arms 18 defining a U-shaped channel 20 therebetween to  
17 receive the rod 10. Inner surfaces of the arms 18 have an  
18 internal guide and advancement structure 22 (Fig. 9) tapped,  
19 or otherwise formed, therein. The head 16 includes grip  
20 indentations 23 (Fig. 9) to facilitate gripping the bone  
21 screw 8 by an appropriate screw gripping tool (not shown)  
22 during manipulation for implantation of the bone screw 8  
23 into the bone 12.

1       The closure body 4 is cylindrical in external shape  
2   about a closure axis 25 (Fig. 7) and has a forward, leading,  
3   or inner end 27 on the bottom and a rear, trailing, or outer  
4   end 28 on the top. The breakaway or breakoff head 6 is  
5   connected to the body 4 at the rear end 28 by way of a  
6   weakened region represented by a breakaway line or ring 30  
7   formed by selectively reducing the wall thickness of the  
8   closure 1 in that region so as to weaken the region. The  
9   breakaway ring 30 is thinned in such a manner that it fails  
10   when a preselected torque is applied to the body 4, as a  
11   result of torque being applied to the head 6 by conventional  
12   socket tools or the like to rotate and tighten the body 4  
13   within the bone screw 8. As illustrated, the break off head  
14   6 has a hexagonal outer surface 31 to facilitate non-slip  
15   engagement by an installation tool (not shown). The head 6  
16   may also be provided with a set of tool slots 32 for  
17   alternative or more positive non-slip engagement of the head  
18   6 by the installation tool. The head 6 has a central and  
19   axially aligned bore 34 that is coaxial with the removal  
20   bore 2 and that defines the break off point of the head 6 in  
21   conjunction with the ring 30 and ends in a chamfer 33.  
22   Separation of the head 6 from the body 4, as shown in Fig.  
23   7, is desirable to control or limit torque applied by the

1 body 4 to the rod 10 within the bone screw head 16,  
2 preferably such that the body 4 is at or below the tops of  
3 the arms 18 so as to present a low profile.

4 The body 4 is provided with a guide and advancement  
5 flange 35 which coaxially extends helically about the  
6 cylindrical body 4. The flange 35 is enlarged at its outer  
7 periphery or radial crest to form a generally inwardly  
8 facing or inward anti-splay surface 37. In a similar  
9 manner, the bone screw guide and advancement structures 22  
10 which are discontinuous but which matingly engage and  
11 receive the body flange 35 are enlarged at their radially  
12 outward peripheries or roots to form generally outwardly  
13 facing or outward anti-splay surfaces 39. The anti-splay or  
14 splay resisting surfaces 37 and 39 face each other and  
15 mutually engage when the body 4 is advanced into the bone  
16 screw head 16 and particularly when the body 4 is strongly  
17 torqued within the head 16 to resist any tendency of the  
18 arms 18 to be urged outwardly, or splayed, in reaction to  
19 such torque.

20 Although particular contours of the flange 35 and  
21 mating structure 22 are shown herein, other contours of  
22 anti-splay guide and advancement flanges and mating  
23 structure are foreseen. Examples of such alternative

1 configurations of anti-splay or splay resisting guide and  
2 advancement flange and mating structures are disclosed in U.  
3 S. Patent application, Serial No. 10/236,123 which is now U.  
4 S. Patent No. \_\_, \_\_\_, \_\_\_, which is incorporated herein by  
5 reference. The flange 35 and mating structures 22 cooperate  
6 to guide and advance the body 4 into clamping engagement  
7 with the rod 10 within the channel 20 in response to  
8 rotation of the closure 1.

9 In order to more positively secure the rod 10 within  
10 the head 16 of the bone screw 8, the closure 4 is provided  
11 with penetrating structure such as a V-ring 42 and an  
12 axially aligned point 43 on the inner or forward end 27  
13 thereof. The V-ring 42 cuts into the surface of the rod 10  
14 when the body 4 is tightly torqued into the head 16. The V-  
15 ring 42 extends about a periphery of the inner end 27 of the  
16 body 4 and, thus, provides two possible areas of engagement  
17 between the body 4 and the rod 10, particularly if the rod  
18 10 is relatively straight and acts with the point 43 to help  
19 secure the rod 10 in the bone screw 8.

20 In the great majority of cases, the body 4 is torqued  
21 into engagement with the rod 10 in the bone screw 8, the  
22 installation head 6 is broken away, and the anchor assembly

1 9 is permanently implanted in the bone 12. However, spinal  
2 alignment geometry is complex, and it is sometimes necessary  
3 to make adjustments to a spinal fixation system.  
4 Additionally, slippage or failure of spinal fixation  
5 components can occur due to injury to the patient,  
6 deterioration of bone tissue, or the like. It is also  
7 possible that an implant system using anchored rods might be  
8 used therapeutically, for example, to set a broken bone, and  
9 subsequently removed. For these reasons, implant anchor  
10 assemblies require a structure or mechanism for removing an  
11 anchor assembly 9 to make such adjustments or changes in the  
12 spinal fixation system. The anchor assembly 9 of the  
13 present invention allows retraction and removal of the  
14 closure body 4 from the bone screw head 16 to release the  
15 rod 10 to allow repositioning of the rod 10 relative to the  
16 bone screw 8 or overall removal of the bone screw 8 and rod  
17 10.

18 The body 4 includes the bore 2 which extends from the  
19 outer surface 28 axially partially therethrough. The bore 2  
20 has an inner cylindrical surface 45 that has a left handed  
21 thread 47 thereon. The bore surface 45 has a short shoulder  
22 48 whereat it engages the top of the body 4 that becomes



1 part of the outer surface 28 when the head 6 breaks from the  
2 body 4.

3 The body 4 is removed from the screw 8 by placement of  
4 a tool 50 (see Fig. 9) having a projection 51 that is joined  
5 to a remainder of the tool 50 by a shoulder 53. The  
6 projection 51 has thereon a left handed thread 55 that is  
7 sized and shaped to mate with the bore thread 47. The tool  
8 50 includes a handle (not shown) or the like to provide for  
9 rotation. When the tool 50 is screwed counterclockwise into  
10 and implanted in the body 4, as shown in Fig. 9, and  
11 thereafter further rotated counterclockwise, the body 4  
12 rotates counterclockwise and moves in an axial and upward  
13 direction (as seen in Fig. 9), so that the body 4 is removed  
14 from the bone screw head 16 and securely held.

15 Although a particular fixed headed bone screw is shown  
16 herein, it is foreseen that the present invention may be  
17 utilized with other types of implants, including polyaxial  
18 head bone screws of all types, hooks and other implants  
19 wherein a channel receives a rod or rodlike member and the  
20 rod requires securing against movement relative to the bone  
21 screw or other implant.

22 It is to be understood that while certain forms of the  
23 present invention have been illustrated and described

1    herein, it is not to be limited to the specific forms or  
2    arrangement of parts described and shown.  
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